Registration Decision RD2015-22

Bacillus amyloliquefaciens strain D747

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Registration Decision for *Bacillus amyloliquefaciens* strain D747

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Bacillus amyloliquefaciens* strain D747 Technical, Double Nickel 55 and Double Nickel LC, containing the technical grade active ingredient *B. amyloliquefaciens* strain D747, to suppress or partially suppress a variety of fungal or bacterial diseases on cucurbits, fruiting vegetables, grapes, lettuce, pome fruit, potato, soybean and strawberry.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-13, *Bacillus amyloliquefaciens* strain D747. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *B. amyloliquefaciens* strain D747 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-13. This decision is consistent with the proposed registration decision stated in PRD2015-13.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-13, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Bacillus amyloliquefaciens* strain D747?

The active ingredient, *B. amyloliquefaciens* strain D747, is a naturally occurring bacterium that is found in close association with roots, leaves and other plant parts. It is reported to prevent the establishment of disease-causing fungi and bacteria by rapidly colonizing plant surfaces. *B. amyloliquefaciens* strain D747 along with granular and liquid formulated end-use products have been registered in the United States since 2011 for the management of a wide range of diseases on various ornamental, horticultural and field crops. Two end-use products containing this active ingredient, Double Nickel 55 and Double Nickel LC, are being registered in Canada for the management of fungal and bacterial diseases on cucurbits, fruiting vegetables, grape, lettuce, pome fruit, potato, soybean and strawberry. They are intended for use as foliar and soil applied treatments.

Health Considerations

Can Approved Uses of *Bacillus amyloliquefaciens* strain D747 Affect Human Health?

***Bacillus amyloliquefaciens* strain D747 is unlikely to affect your health when Double Nickel 55 and Double Nickel LC are used according to the label directions.**

People could be exposed to *B. amyloliquefaciens* strain D747 when handling and applying Double Nickel 55 and Double Nickel LC, and when ingesting treated produce. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic by-products);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When the technical grade of the active ingredient as well as granular and liquid formulations containing *B. amyloliquefaciens* strain D747 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based maximum residue limits to ensure that the food Canadians eat is safe.

Residues of *B. amyloliquefaciens* strain D747 on the treated crops, at the time of harvest, are anticipated following foliar applications to agricultural crops. *B. amyloliquefaciens* is a bacterium that is found globally in most terrestrial environments. *B. amyloliquefaciens* strain D747 produced no adverse effects (disease or toxicity) when it was administered orally to rats and it is not known to produce metabolites of toxicological concern. Also, no adverse effects have been reported for this microorganism in the United States where it has been registered as a pesticide since 2011. As well, the likelihood of residues of this microorganism contaminating drinking water supplies is considered to be low. Consequently, dietary risks are considered to be low and not of concern. Therefore, the PMRA has determined that the specification of a maximum residue limit under the *Pest Control Products Act* is not required for *B. amyloliquefaciens* strain D747.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Double Nickel 55 and Double Nickel LC are proposed for use on agricultural crops only. The application directions on the product labels include statements to minimize spray drift. Consequently, it is unlikely that adults, youths and toddlers will be exposed to *B. amyloliquefaciens* strain D747. Even in the event of exposure, risk to the general population is not a concern since there were no signs of disease or toxicity noted in toxicological studies with this microorganism.

Occupational Risks from Handling Double Nickel 55 and Double Nickel LC

Occupational risks are not of concern when Double Nickel 55 and Double Nickel LC are used according to label directions, which include protective measures.

Workers handling Double Nickel 55 and Double Nickel LC can come into direct contact with *B. amyloliquefaciens* strain D747 on the skin, in the eyes or by inhalation. For this reason, the product label will specify that workers exposed to the end-use products must wear waterproof gloves, long-sleeved shirts, long pants, a National Institute for Occupational Safety and Health-approved (NIOSH-approved) mist filtering mask or respirator with any N-95, P-95, or R-95

filter, and shoes plus socks. Eye goggles are not required as the eye irritation studies indicated minimal eye irritation potential.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Bacillus amyloliquefaciens* strain D747 Is Introduced Into the Environment?

Environmental risks are not of concern.

B. amyloliquefaciens is commonly found in soil. Information available in the scientific literature on the environmental fate of *B. amyloliquefaciens* indicates that, like all *Bacillus* species, *B. amyloliquefaciens* strain D747 produces endospores under adverse environmental conditions that allow it to survive under extreme heat and dry conditions. The ability to produce endospores is a major factor in the widespread occurrence of the organism in soil environments. However, most endospores are sensitive to sunlight and consequently *Bacillus* species are not widely found on plant surfaces. While the population of *B. amyloliquefaciens* strain D747 will be above levels naturally found for this species immediately following application as a pesticide, the population will settle back to natural levels over time.

B. amyloliquefaciens may survive to a limited extent in aquatic habitats given its ability to produce endospores and their potential to adsorb to the sediment layer. Endospores, however, are unlikely to be capable of germinating and multiplying in sediment. Double Nickel 55 and Double Nickel LC are not intended for aquatic use and exposure to aquatic environments from spray drift and runoff (following a rain event) from field application is unlikely to be significant. Studies were conducted to determine the effects of *B. amyloliquefaciens* strain D747 on birds, terrestrial arthropods (including bees), and plants, as well as fish and aquatic invertebrates. These studies showed that *B. amyloliquefaciens* strain D747 was not toxic or pathogenic to these organisms.

Although non-target testing was not conducted on wild mammals, microorganisms and aquatic plants, adequate information was available in the scientific literature to determine that no significant adverse effects to these non-target organisms are expected when Double Nickel 55 and Double Nickel LC are applied according to directions on the label.

Value Considerations

What Is the Value of Double Nickel 55 and Double Nickel LC?

Double Nickel 55 and Double Nickel LC are broad spectrum biological fungicides/bactericides that suppress diseases on a wide range of host plants.

These products can be a valuable addition to sustainable disease management programs and organic production systems in Canada. The bacterial active ingredient in Double Nickel 55 and Double Nickel LC rapidly colonizes plant surfaces and impedes the development of plant-pathogenic organisms through resource competition and production of antagonistic defence metabolites. Most effective when applied preventatively, these products have been shown to reduce the incidence and severity of different economically important diseases under various levels of pest pressure. Because of the complex nature of its mode of action, resistance to the active ingredient is unlikely to develop and would be useful in an integrated disease management program.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the labels of Double Nickel 55 and Double Nickel LC to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed repeatedly to potentially large quantities of Double Nickel 55 and Double Nickel LC, respiratory and dermal sensitivity may possibly develop. All microorganisms, including *B. amyloliquefaciens* strain D747, contain substances that are potential sensitizers. Therefore, anyone handling or applying these products must wear appropriate waterproof gloves, a long-sleeved shirt, long pants, a NIOSH-approved mist filtering mask or respirator with any N-95, P-95, or R-95 filter, and shoes plus socks.

Environment

The end-use product labels will include environmental precaution statements that prevent the contamination of aquatic systems from the use of Double Nickel 55 and Double Nickel LC.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-13, *B. amyloliquefaciens* strain D747) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.